



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/472,558	12/27/1999	MOHAMMAD B. BAHRAMIAN	2281/102	8925

2101 7590 02/05/2003

BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 02/05/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/472,558

Applicant(s)

BAHRAMIAN ET AL.

Examiner

Peter Paras, Jr.

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on ____ Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): ____.
4. ☐ Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.


Claim(s) rejected: 11,13-18,22-25 and 57-67.

Claim(s) withdrawn from consideration: 28-49,51 and 53-56.

8. ☐ The proposed drawing correction filed on 13 December 2002 is a) ☒ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). ____.

10. ☐ Other: See Continuation Sheet


MICHAEL WILSON
PRIMARY EXAMINER

Continuation of 2. NOTE: the claims as amended contain the recitation "or having the capacity to become double-stranded upon delivery to the population of cells", which appears to be new matter. The sections of the specification (p 3, lines 18-19, p29, lines 12-16, and p30 lines 3-24, particularly lines 15-20) pointed to by Applicant in support of the above recitation do not discuss a muting nucleic acid composition having the capacity to become double-stranded upon delivery to the population of cells. Also, the same recitation raises issues that require further consideration and a new search as it has never been recited in claims. In addition, Applicants have added new claims 68-71 but have only cancelled claim 25.

Continuation of 5. does NOT place the application in condition for allowance because: the proposed amendments to the claims fail to overcome the rejection under 112, first paragraph, enablement. Applicants have argued that mechanism of muting must be a general effect which occurs via small dsRNA molecules that are generated from the degradation of large heterogeneous antisense RNA molecule which have hybridized with mRNA from the endogenous gene triggering degradation of mRNA of the endogenous gene. In response, the Examiner maintains that the evidence of record does not suggest the mechanism of muting. As such it is not known whether or not the mechanism of muting is general as stated in the previous Office action on page 5. The specification on page 30 discusses that the mechanism is not related to antisense. See lines 23-24. In light of such, Applicant's suggestion that the mechanism of muting involves antisense RNA appears to be contradictory to the teachings of the specification. Moreover, there does not appear to be support for the basis of Applicant's arguments in the specification. Finally, Applicants arguments also appear contradictory to the claims, in light of the claim breadth of a nucleic acid molecule of any type. If for example, the claimed nucleic acid is dsDNA and the claim requires that muting is independent of integration, expression or transcription of the delivered muting nucleic acid then it does not appear possible to obtain dsRNA, comprising endogenous mRNA and antisense RNA, as Applicants are arguing. The source of the antisense appears to be unknown since it cannot be transcribed from the muting nucleic acid. Applicants have argued that RNA and DNA analogs are well known in the art and can be easily used in place of DNA or RNA. In response, the Examiner maintains that there are no teachings, guidance, or working examples provided by the evidence of record that suggest muting is achieved with RNA or DNA analogs. See page 6 of the final office action mailed on 8/13/02. Applicants have argued with regard to claim 23 if the RNA is made as a transcript, then the claim is understood or if RNA arises in the cell then it arises from initial cellular production of 3' antisense RNA. In response, the Examiner asserts that muting nucleic acid molecules cannot be transcribed after delivery to the cells. The Examiner also asserts that the evidence of record does not support the muting nucleic acid molecule as being homologous to an endogenous 3' antisense RNA molecule. Accordingly, the rejection is maintained for the reasons of record.

Since the proposed amendment has not been entered all the rejections under 35 U.S.C. 102 have been maintained for the reasons of record. See pages 10-17 of the office action mailed on 8/13/02.

Continuation of 10. Other: The instant application is now in sequence compliance. The remarks, on page 2 of the amendment, with regard to which claims have been amended appear to contain a typographical error to the extent that claim 64 was indicated as amended however, an amended version of the claim, either in clean or marked up form, has not been submitted. Also, it appears that Applicants have submitted two different versions of proposed amendments after final, one is signed and one is unsigned. For the purpose of this advisory action the Examiner is considering only the signed proposed amendment.